

JUL 31 2001

K011522



Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Mary L. Verstynen
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Resorbable Bone Pins

Common Name: fixation pin or rod

Classification Name: Pin, Fixation, Smooth, Non-metallic (888.30440)

Legally Marketed Device To Which Substantial Equivalence Is Claimed:
LactoSorb® Bone Pin

Device Description: The Resorbable Bone Pins are made of completely resorbable material comprised of L-lactide/glycolide copolymer. The pins range in diameter size 1.5 – 3.2mm and in lengths 20 – 70mm. Either a Steinmann pin or Kirschner wire (K-wire) are used to drill a pilot hole through which the pin is then inserted. Upon insertion, the pins can be cut using a heat loop.

Intended Use: The Resorbable Bone Pins are indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus
2. repair of metacarpal and phalangeal fusion and fractures

Summary of Technologies: The Resorbable Bone Pins have the same design and a similar material as the predicate devices.

Non-Clinical Testing: *In-vitro* testing determined the Resorbable Bone Pins were equivalent or better in shear and bend strength when compared to the predicate device.

Clinical Testing: Non-applicable

All trademarks are property of Biomet, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 31 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary L. Verstynen
Manager of Clinical Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011522
Trade Name: Resorbable Bone Pins
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HTY and MAI
Dated: May 05, 2001
Received: May 17, 2001

Dear Ms. Verstynen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Devices Evaluation

Center for Devices and

Radiological Devices

Enclosure

510(k) NUMBER (IF KNOWN): K011522

DEVICE NAME: Resorbable Bone Pins

INDICATIONS FOR USE:

The Resorbable Bone Pins are indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus
2. repair of metacarpal and phalangeal fusion and fractures

[Signature]

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K011522

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)